

Amendment and Response

Applicant: Timothy R. Ryan et al.

Serial No.: 09/982,299

Filed: October 16, 2001

Docket No.: M190.137.101

Title: ANNULOPLASTY BAND AND METHOD

REMARKS

This Amendment is responsive to the Office Action mailed August 11, 2004. In that Office Action, the Examiner rejected claims 1-9, 44, and 45 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1-4, 7, 9-13, 15, 16, and 37-43 were rejected under 35 U.S.C. §102(b) as being anticipated by Wright et al., U.S. Patent No. 5,306,296 (“Wright”). Claims 5, 6, and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wright as applied to claims 1, 4, and 7 above, and further in view of Carpentier et al., U.S. Patent No. 5,061,277 (“Carpentier”). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Wright as applied to claim 1 above, and further in view of Loch et al., U.S. Patent No. 6,174,332 (“Loch”). Claims 30 and 33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wright as applied to claim 1 above, and further in view of Howanec, Jr., et al., U.S. Patent No. 6,183,512 (“Howanec”).

With this Response, claims 30 and 33 have been canceled; claims 1, 44, and 45 have been amended; and claims 46 and 47 have been added. Claims 1-16 and 37-47 remain pending in the application and are presented for consideration and allowance.

35 U.S.C. §112, first paragraph, Rejections

By this Amendment and Response, the language specified by the Examiner in rejecting claims 1 and 44 under 35 U.S.C. §112, first paragraph, has been removed, thus traversing the rejections.

With respect to claim 45, the Examiner states that the term “intermediate section” in the claim is not consistent with the definition of “intermediate section” in the specification, and that “first point”, “second point”, and “linear distance” as used in claim 45 are “therefore not described in the specification”. In response, the Examiner’s attention is respectfully directed to page 11, lines 20 – 24 and claims 7 and 8 where the phrase “intermediate portion” is used (as opposed to “intermediate section”). Notwithstanding this difference, claim 45 has been amended to replace “intermediate section” with “middle section”. Taken in context, it appears that the Examiner’s statement that “the first and second points and the linear distance, as used in claim 45, are therefore not described in the specification” (emphasis added) is a conclusion resulting

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from the Examiner's concern with the "intermediate section". In other words, the Examiner appears to state that because "intermediate section" is inconsistent with the specification, therefore "the first and second points and the linear distance" are not described in the specification. As such, it is believed that amending the term in question to "middle section" fully traverses the Examiner's rejection of claim 45 under 35 U.S.C. § 112, first paragraph.

Additionally, it is noted that the written description requirement as applied to claim limitations can be satisfied by the specification through express, implicit or inherent disclosure. MPEP §2163. Further, the drawings alone can provide "written description" of an invention as required by 35 U.S.C. §112, first paragraph. MPEP §2163 II.A.3.a. With this in mind, it is respectfully submitted that at least FIGS. 1 and 3 implicitly or inherently discloses the limitations of amended claim 45. In both figures, the eyelets are linearly closer to one another than are points adjacent each eyelet. One of ordinary skill in the art will readily interpret FIGS. 1 and 3 to implicitly or inherently disclose a stiffening element having middle section and opposing first and second eyelets, points being defined at the transition of the middle section to the first eyelet and the second eyelet, and that a linear distance between these transition points is greater than a linear distance between the eyelets. For at least these reasons, it is respectfully requested that the rejection of claim 45 under 35 U.S.C. § 112, first paragraph, be withdrawn.

35 U.S.C. §§ 102, 103 Rejections

Claim 1 has been amended to recite that upon assembly, a maximum transverse width of the sheath at the first and second eyelet ends of the stiffening element is greater than a maximum transverse width of a remainder of the sheath. Support for this language is found, for example, in FIGS. 1 (where, for example, the "transverse width" as used in claim 1 is the dimension represented by the line "2-2"), 3 and 8 where the sheath 44 has a maximum transverse width at the eyelets 50, 52 that is greater than a maximum transverse width of a remainder of the sheath. Wright does not teach or suggest at least this limitation. In particular, as shown in FIG. 2 of Wright, the sheath 11 narrows in transverse width at the eyelets 36, 37. In fact, the greatest transverse width of the sheath 11 is provided at the seam 12, a portion of the sheath that is otherwise discernibly spaced from the eyelets 36, 37. Notably, this is a required characteristic of

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Wright in that the area of the sheath otherwise adjacent the seam 12 (relative to the orientation of FIG. 1) is inherently wider than all other portions as multiple loops of the drawstrings 20, 21 are contained within this area. For at least this reason, it is respectfully submitted that amended claim 1, and claims 2-9 depending therefrom, are allowable over the cited references.

With respect to independent claim 10, the Examiner has repeated the single sentence reasoning set forth in the Final Office Action of February 11, 2004 (that Wright discloses “markers 38 are located at the eyelets”). In doing so, the Examiner has failed to address the amendment to claim 10 provided in the Amendment and Response of May 11, 2004, along with the corresponding arguments. To this end, the Examiner’s initial comment that “Applicant’s arguments with respect to claim [10] have been considered but are moot in view of the new ground(s) of rejection” (Office Action, page two, unnumbered first paragraph) is not understood as the current Office Action does not provide any new ground(s) of rejection for claim 10.

Applicant respectfully requests that the Examiner examine claim 10 and consider the arguments presented in the May 11, 2004 Amendment and Response. In sum, elements 38 and 39 of Wright are stitchings (col. 16, lines 4-10). The stitchings 38, 39 are continuous about an entire circumference of the sheath 11 (see, for example, FIG. 1 of Wright in which the stitching 39 is continuous along the entire circumference). Thus, the continuous stitching are not discrete markings that correspond to the positions of the first and second eyelets, as otherwise required by claim 10. Thus, claim 10, and claim 11 depending therefrom, recite allowable subject matter.

With respect to independent claim 37, it is again respectfully asserted that the Examiner has not considered the amendments and corresponding arguments set forth in the Amendment and Response of May 11, 2004. No new ground(s) for rejecting claim 37 are presented in the current Office Action, and Applicant respectfully requests that the previous amendment and arguments be examined. The Examiner has not specified how the continuous stitching 38 of Wright identifies an eyelet position. In fact, the continuous stitching 38 does not and cannot identify a position of the eyelet 36 or 37. FIG. 10 of Wright clearly illustrates this fact; it is impossible to discern eyelet position within the sheath 11 via the continuous stitching 38 upon studying FIG. 10. Thus, the marker 38 of Wright does not teach or suggest the visible marking

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limitation of claim 37, such that claim 37, and claims 38-43 depending therefrom, recite allowable subject matter.

Independent claim 44 has been amended to recite that an entirety of a perimeter shape of the sheath is defined by the stiffening element. Support for this language is found, for example, in FIG. 1. Wright does not teach or suggest at least this language. Thus, it is respectfully submitted that amended claim 44 recites allowable subject matter.

With respect to independent claim 45, claim 45 was rejected only under 35 U.S.C. §112, first paragraph, and this rejection has been traversed for the reasons described above. In the absence of any art-based rejections, it is respectfully assumed that the Examiner views claim 45 as allowable over the cited references. To the extent the Examiner intends to raise a new rejection based on Wright, Applicant incorporates the arguments presented the May 11, 2004 Amendment and Response in which the failure of Wright to meet the limitations of claim 45 is set forth.

Newly Presented Claims

Newly presented claim 46 depends from claim 37 and thus, for at least the reasons described above, is allowable. In addition, claim 46 recites that the visible marking is a cross. Support for this language is found, for example, at page 13, lines 4-5 and FIG. 1. The continuous stitching 38 of Wright clearly does not teach or suggest this limitation, such that newly presented claim 46 recites additional patentable subject matter.

Newly presented claim 47 is directed to an annuloplasty device comprising a reinforcing member and a sheath. The reinforcing member forms opposing, first and second eyelets. The sheath entirely encompasses the reinforcing member and defines closed, first and second ends corresponding with the first and second eyelets, respectively. Support for this language is found, for example, in FIG. 1 and corresponding specification discussion. None of the cited references teach or otherwise suggest these limitations. For example, the continuous, tubular sheath 11 of Wright does not form first and second closed ends corresponding with the first and second eyelets. Thus, it is respectfully submitted that newly presented claim 47 recites allowable subject matter.

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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-16 and 37-47 are in form for allowance and are not taught or suggested by the cited references. Notice to the effect is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

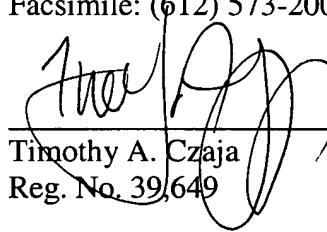
Respectfully submitted,

Timothy R. Ryan et al.,

By their attorneys,

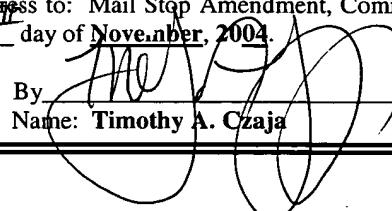
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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10/11 day of November, 2004.


By
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